REMARKS

Upon entry of this amendment, claims 1-25, 27-43, 47-66, and 68-72 will be pending in this application. Claims 1-18, 21-25, 27, 29-43, 45-66, and 68-71 stand withdrawn as directed to non-elected subject matter. Claims 26, 44, and 67 are canceled herein without prejudice or disclaimer. Claims 19 and 28 are amended herein without the addition of new matter. Claim 72 is newly added, and does not introduce new matter. The specification is amended to correct the description of the drawings. These amendments address the objection to the drawings, and do not introduce new matter. It is believed that these amendments to the specification obviate the need to submit amended drawings.

The office action requests that Applicants provide a concise statement of the relevance of particular statements within particular references. Applicants are aware of no such requirement. MPEP § 609 provides that "[a]n information disclosure statement filed in accordance with the provisions of 37 CFR 1.97 and 37 CFR 1.98 will be considered by the examiner assigned to the application." See also MPEP § 609.05. As the information disclosure statement submitted to date complies with the requirements of 37 C.F.R. §§ 1.97 and 1.98, no further information regarding the cited references is required. Applicants respectfully request consideration of the references submitted by way of information disclosure statement.

Claims 19-20, 26, 28, 44, and 67 stand rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. According to the office action, the specification does not support the full genus of genes involved with antibody production, does not support the scope of modulating, and does not support the genus of targeting vectors to AAT and/or EMAP genes. Applicants disagree with the rejection. To facilitate prosecution, and without prejudice to acting otherwise in continuing applications, applicants have amended claim 19 to recite that the method comprises suppressing the expression of alpha-l-anti-trypsin, endothelial monocyte-activating polypeptide I, or both, as supported throughout the specification.

The genus of AAT and EMAP genes, is adequately described. The claims as amended are directed to the suppression of AAT and EMAP genes, and provide a functional limitation of enhancing antibody expression. The disclosure demonstrates that at least one

gene in each of the AAT and EMAP families, when suppressed, enhances antibody expression. In light of the functional limitation, Applicants submit that a reasonable and representative number of species have been described, certainly enough to justify claims to the genus. This is not a case of extraordinarily large number of genes within the family. Moreover, AAT and EMAP genes/sequences are known and readily identified by those of skill in the art. Thus, sufficient structure (AAT or EMAP gene) and function (enhanced antibody expression upon gene suppression) are provided. Accordingly, those of skill in the art would understand that Applicants are in possession of those particular members of the AAT and/or EMAP gene family that enhance antibody expression upon their respective suppression. The particular AAT and EMAP genes can be suppressed according to the inventive methods.

As concerns the structure of knock-out vectors, Applicants submit that knock out technology was well established at the time the invention was filed. In addition, Applicants submit that many AAT and EMAP genes are characterized and known in the art. It is thus within the skill in the art to identify AAT and/or EMAP gene sequences, including those particular to a given organism such as a mouse, rat, or human, and to devise suitable knockout vectors that could specifically disrupt the expression of particular AAT or EMAP genes. Moreover, it is within the skill in the art to identify common sequences/regions among the members of AAT and EMAP gene families in order to devise knockout vectors that can specifically and simultaneously target multiple AAT or EMAP genes, including the five mouse genes identified by the office action. Applicants submit that the information provided by the instant disclosure, coupled with the broad knowledge of knock out technology established in the art, provides sufficient structure (AAT and EMAP genes) and function (knockout) to inform those of skill in the art that the Applicants were in possession of the full scope of the invention as claimed.

For these reasons, Applicants submit that the claims are adequately described, and thus request reconsideration and withdrawal of the rejection.

Claims 19-20, 26, 28, 44, and 67 stand rejected under 35 U.S.C. §112, first paragraph as allegedly not enabled by the specification. According to the office action, the specification does not enable the modulation of gene expression, the full genus of genes involved with antibody production, or the knockout of AAT or EMAP expression on the grounds that a

phenotype for successful knockout is allegedly not disclosed. Applicants disagree with the rejection.

As described in more detail above, the claims are amended to reflect that the method comprises suppressing the expression of AAT, EMAP, or both. Applicants submit that it is not undue experimentation to suppress AAT or EMAP genes, particularly in light of the diverse methods demonstrated to be successful in the Examples in the instant application. Moreover, given the relatively small number of AAT and EMAP genes, it is not undue experimentation to determine if the suppression of a given AAT or EMAP gene results in enhanced antibody expression.

With respect to the issue of the phenotype of an AAT or EMAP knockout, Applicants submit that at the time the invention was made, knockout technology was sufficiently enabled to permit those of skill in the art to practice the claimed invention based on the instant disclosure without undue experimentation. First, it bears noting that the specification in fact describes a particular phenotype that can be screened for, namely, enhanced antibody expression. It is well within the skill in the art to determine, using routine experimentation, whether a particular cell type that has been transformed with a knockout vector expresses higher levels of antibodies relative to counterpart cells that have not been transformed with a knockout vector. Other methods, however, are known and routinely practiced in the art for tracking a successful knockout. For example, as was routinely practiced at the time the invention was filed, reporter genes can be provided with the knockout vector. The reporter gene can be a selectable marker, or visible marker such as GFP. The reporter gene is not critical, and can be selected based on the needs of the investigator. Thus, the claims are fully enabled by the specification in conjunction with what was known and routinely practiced in the art at the time the invention was made. Accordingly, Applicants are in compliance with the enablement requirement, and reconsideration and withdrawal of the rejection is requested.

Claims 19, 26, and 44 stand rejected under 35 U.S.C. §112, second paragraph for alleged indefiniteness. The office action states that the terms "modulate" and "associated with" are not defined, and thus render the claims indefinite. Applicants disagree. Claims 26 and 44 are canceled herein. Claim 19 is amended to even more clearly define the claimed subject matter.

Claims 19-20 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Bloemkolk. The office action states that Bloemkolk teaches a method to enhance antibody production by arresting cells at the G1 phase of the cell cycle, thereby reading on the instant limitation of "modulating." Applicants disagree with the rejection. Bloemkolk does not teach or suggest the suppression of AAT or EMAP genes. Thus, the limitations of the claimed invention are not provided by the cited art. Withdrawal of the rejection is warranted.

In view of the amendments submitted herewith and the foregoing remarks, applicants respectfully assert that all claims presently pending are in condition for allowance. Favorable reconsideration and a Notice of Allowance are earnestly requested.

Respectfully Submitted,

Date: January 22, 2007

/Felicity E. Groth/
Felicity E. Groth
Registration No. 47,042

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439